

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Satishchandra P. Patel

U.S. Patent Application Serial No.: 10/632,970

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Title: PHARMACEUTICAL COMPOSITIONS

DECLARATION UNDER RULE 132

SATISHCHANDRA P. PATEL, declares that

1. I am the applicant in the above identified application.
2. The experimental work described in the examples of the above identified application were done by or for me and gave the results therein set forth.
3. The Mulye reference which has been cited by the Examiner relates to the use of a propylene glycol ester of a 6 to 18 carbon atom fatty acid of which at least 60% by weight based on the total weight of the propylene glycol ester is monoester. It states that a content of at least 60% monoester is essential and that the diesters do not aid in solubilizing a lipophilic drug. In Comparative Example 1, it is shown that a formulation containing 10% monoester precipitates and crystallizes after one week and in Comparative Example 2, a composition in which the monoester content is about 45 to 50 percent precipitated with crystal growth after two weeks.
4. I discovered that when the esters are of fatty acids having from 8 to 10 carbon atoms and the monoester is between 50 and 60 mol percent of the mixture of the mono- and diesters, surprising and unexpected effects were realized. These results were not predictable.
5. For instance, as shown in my Example 1, a composition containing mono- and diesters with caprylic acid in which the monoester content was between 50 and 60% provided an initial clear solution and the solution remained clear when stored for four weeks at either 25°C or 40°C.

In Mulye's Comparative Example 1, a mixture of esters of the same fatty acid in which the monoester was 10% showed crystallization and precipitation after one week at 25°C as opposed to my invention where a clear solution was maintained for at least 4 weeks at the same temperature at a monoester content between 50 and 60%. The fact that increasing the monoester content to between 50 and 60% did not result in precipitation and crystallizing is surprising, unexpected and unpredictable, particularly since the reference indicates that the monoester content must be at least 60%, and preferably much higher, in order to achieve this result. Comparative Example 2 in my application shows that similar good storage results were not achieved when a 12 carbon atom fatty acid was used as the esterifying agent and this result further shows the result when an 8 to 10 carbon atom fatty acid is used is surprising, unexpected and unpredictable.

5. Hygroscopicity tests were carried out with compositions in which the propylene glycol ester was a mixture of mono- and diesters of C₈ fatty acid. When the monoester content was about 90%, which is indicated to be the most preferred amount in the Mulye reference, the absorption of moisture from a soft gel capsule was 3-4% whereas when the monoester content was between 50 and 60%, the absorption was only 1-2% moisture. This reduced moisture absorption is also surprising, unexpected and unpredictable.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

8 August
Dated: May 2007



Satishchandra P. Patel